§ 118.3 Movement of detained biological products; Termination of detention.

Except as provided in paragraphs (a) and (b) of this section, no biological product detained in accordance with the provisions in this part shall be moved by any person from the place at which such product is located when it is detained.

(a) A detained biological product may be moved from the place at which it is located when so detained for the purpose of providing proper storage conditions if such movement has been approved by an authorized representative of the Administrator; *Provided*, That, the biological product so moved shall be detained by an authorized representative of the Administrator after such movement.

(b) A detained biological product may be moved from the place at which it is detained on written notification by an authorized representative of the Administrator that the detention is terminated; *Provided*, That, the conditions under which the detained biological product may be moved will be specified in the written notification of the termination. The notification of termination shall be served by either personally delivering the notification, or by certifying and mailing the notification addressed to such person at the last known residence or principal office or place of business of the owner, agent, or other person having custody of the biological product.

[52 FR 30135, Aug. 13, 1987, as amended at 56 FR 66784, Dec. 26, 1991]

§ 118.4 Seizure and condemnation.

Any biological product which is prepared, sold, bartered, exchanged, or shipped in violation of the Act or regulations shall be liable to be proceeded against and seized and condemned, at any time, on a libel of information in any United States district court or other proper court within the jurisdiction of which the product is found. If the product is condemned, it shall, after entry of the decree, be disposed of by destruction or sale as the court may direct, and the proceeds, if sold, less the court costs and fees, and storage and other proper expenses, shall be paid into the Treasury of the United States, but the product shall not be sold contrary to the provisions of the Act or the laws of the jurisdiction in which it is sold; *Provided*, That, upon the execution and delivery of a good and sufficient bond conditioned that the product shall not be sold or otherwise disposed of contrary to the provisions of the Act or the laws or jurisdiction in which disposal is made, the court may direct that such product be delivered to the owner thereof subject to such supervision by authorized representatives of the Administrator as is necessary to ensure compliance with the applicable laws. When a decree of condemnation is entered against the product and it is released under bond, or destroyed, court costs and fees, and storage and other proper expenses shall be awarded against the person, if any, intervening as claimant of the product. The proceedings in such libel cases shall conform, as nearly as may be practicable, to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

[52 FR 30135, Aug. 13, 1987, as amended at 56 FR 66784, Dec. 26, 1991]

PART 121—POSSESSION OF BIOLOGICAL AGENTS AND TOXINS

Sec.

AUTHORITY: Secs. 211–213, Title II, Pub. L. 107–188, 116 Stat. 647 (7 U.S.C. 8401).

SOURCE: 67 FR 52388, Aug. 12, 2002, unless otherwise noted.

EFFECTIVE DATE NOTE: At 67 FR 76931, Dec. 13, 2002, part 121 was revised, effective Feb. 11, 2003. For the convenience of the user, the text effective Feb. 11, 2003 is set forth following the current text.

§ 121.1 Definitions.

Biological agent. Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such

microorganism or infectious substance, capable of causing:

(1) Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;

(2) Deterioration of food, water, equipment, supplies, or material of any kind; or

(3) Deleterious alteration of the environment.

Facility. Any individual or government agency, university, corporation, company, partnership, society, association, firm, or other legal entity located at a single geographic site that may transfer or receive through any means a biological agent or toxin subject to this part.

Overlap agent or toxin. A microorganism (including a virus, bacterium, fungus, rickettsia) or toxin that poses a risk to both human and animal health and that is listed in §121.2(a). The term also includes:

(1) Genetically modified microorganisms or genetic elements from organisms listed in §121.2(a), shown to produce or encode for a factor associated with a disease; and

(2) Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in §121.2(a), or their toxic subunits.

Person. Any individual, firm, corporation, company, society, or association; any Federal, State, or local governmental entity; or any organized group of any of the foregoing.

Responsible facility official. An official authorized to transfer and receive biological agents or toxins, including overlap agents and toxins, covered by this part on behalf of a facility. This person should be either a safety officer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives a biological agent or toxin at the facility.

Toxin. The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes:

(1) Any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or

(2) Any poisonous isomer or biological product, homolog, or derivative of such a substance.

[67 FR 52388, Aug. 12, 2002, as amended at 67 FR 60520, Sept. 26, 2002]

§121.2 List of biological agents and toxins.

The biological agents and toxins listed in this section have been determined to have the potential to pose a severe threat to both human and animal health, to animal health, or to the production and marketability of animal products. Unless exempted under paragraph (c) of this section, any person who possesses any listed agent or toxin or, in the case of a listed disease, the causative agent of that disease, must notify the Animal and Plant Health Inspection Service of that possession in accordance with §121.3.

(a) *Overlap agents and toxins.*

(1) *Bacillus anthracis.*

(2) *Brucella abortus, B. melitensis, B. suis.*

(3) *Burkholderia (Pseudomonas) mallei.*

(4) *Burkholderia (Pseudomonas) pseudomallei.*

(5) *Clostridium botulinum.*

(6) *Coccidioides immitis.*

(7) *Coxiella burnetii.*

(8) Eastern equine encephalitis virus.

(9) Equine morbillivirus (Hendra virus).

(10) *Francisella tularensis.*

(11) Rift Valley fever virus.

(12) Venezuelan equine encephalitis virus.

(13) Aflatoxins.

(14) Botulinum toxins.

(15) *Clostridium perfringens* epsilon toxin.

(16) Shigatoxin.

(17) Staphylococcal enterotoxins.

(18) T–2 toxin.

(b) *Animal agents and toxins.*

African horsesickness virus
African swine fever
Akabane virus
Avian influenza (highly pathogenic)
Bluetongue virus (exotic)
Bovine spongiform encephalopathy agent
Camel pox virus
Classical swine fever